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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,151	09/20/2005	Richard Melville France	113046-003US1	1048

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PROCOPIO, CORY, HARGREAVES & SAVITCH LLP
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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1657

NOTIFICATION DATE	DELIVERY MODE
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07/01/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@procopio.com
PTONotifications@procopio.com

Office Action Summary	Application No. 10/550,151	Applicant(s) FRANCE ET AL.	
	Examiner David M. Naff	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A response of 4/30/09 to a restriction requirement of 4/3/09 elected Group II claim 34 without traverse, canceled Group I claims 1-18, and added new claims 35-51. Claims 19-33 have been previously canceled.

5 Claims examined on the merits are 34-51, which are all claims in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

10

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15

Claims 34-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

20

The specification fails to contain an adequate description of using a fluid other than a liquid as the first phase. Working conditions have not been provided of using a gas or a solid in the form of a powder or granules as a first phase fluid. When the first phase is a gas, powder or granules, the specification does not provide any details of how to form a solidifiable matrix as claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

25

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5 In line 1 of claim 34 and where recited in other claims, "solidifiable matrix" is confusing and unclear since first phase is fluid. A fluid is not a matrix. A matrix has structure and form, which a fluid does not have.

The claims are confusing and unclear by claim 34 being unclear as to form of a solid that is fluid that flows and conforms to the outline of a container. Solids are normally not considered to be a fluid that flows, and conform to the shape of a container.

10 Claim 34 is unclear by not having clear antecedent basis for "their container" (last line). A container has not been previously required. Furthermore, requiring conforming to a container outline is confusing since the solidifiable matrix is introduced into a tissue prior to solidification. There would be no reason for the fluid conforming to the outline of a container prior to introducing into the tissue since a container is not introduced into tissue, or a container is not
15 used in preparing the matrix.

Claim 34 is unclear where the second phase is relative the first phase after solidification to form a porous matrix. Is the second phase distributed in the porous matrix?

Claims 38-41 are unclear how both phases can comprise the same polymer as encompassed by the claims, and provide first and second phases as required by the claims. If
20 both phases contain the same polymer, there will be only a single phase.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

25 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

Art Unit: 1657

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later
10 invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 34-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jeong et al (6,841,617) in view of Sheplan et al (6,290,729), and if necessary in further view of Sawhney (6,818,018) or Hubbell (6,129,761).

15 The claims are drawn to a solidifiable matrix comprising a first phase in a fluid state and a second phase distributed through the first phase. The matrix is suitable for introduction into tissue prior to solidification of the first phase to form a porous matrix.

Jeong et al disclose delivering cells for tissue repair by providing a thermogelling aqueous polymer solution comprising cells at a temperature below the gelling temperature of the
20 polymer, and introducing the solution into a warm blooded animal where the body temperature of the animal is above the gelling temperature of the animal to form a gel containing cells that serves as a scaffold for tissue repair (col 7, lines 24-27 and lines 41-49). The polymer solution introduced into the animal has flowability to fill any shape of a defect (col 4, lines 18-27).

Sheplan et al disclose thermoreversible polymer solutions that are liquid at an elevated
25 temperature, but gelled at body temperatures (col 5, lines 10-15). Cells can be added to liquid polymer solution, and the solution forms a gel at a tissue surface where the cells grow and

Art Unit: 1657

proliferate (col 8, lines 44-46). Composites of increased strength can be formed by incorporation of water insoluble particles (col 7, lines 25-27). Polymer particles can also be incorporated to direct cell growth (col 8, lines 34-35).

It would have been obvious to add polymer particles to the polymer solution of Jeong et al prior to gelling in an animal to provide in the animal a composite gel having increased strength and which directs cell growth as suggested by Sheplan et al. The polymer solution is inherently a first phase in a fluid state and the particles are inherently a second phase, and the mixture of the polymer solution and particles is inherently a solidifiable matrix suitable for introduction into tissue prior to solidification of the first phase. When the polymer solution of Jeong et al contains polymer particles as suggested by Sheplan et al, gelling of the polymer solution in an animal will inherently result in a porous matrix. Sawhney (col 29, lines 1-29) discloses a hydrogel system containing a thermoreversible polymer for forming a medical implant, and Hubbell discloses providing a cell growth template in an animal by gelling a hydrogel in the animal by temperature change (col 8, line 58, and col 11, line 67). If needed, these references would have further suggested conditions that can be used when using a thermoreversible polymer to provide a gel *in situ* in an animal. The conditions of dependent claims would have been matters of choice dependent on individual preference within the skill of the art in view of the disclosures of the references.

Response to Arguments

Arguments in the amendment of 1/6/09 are moot in view the different invention now claimed, and the different references applied.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

5 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications
10 may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the
15 automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/
Primary Examiner, Art Unit 1657

6/27/09
DMN